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GILEAD | Medical Information

Trodelvy® (sacituzumab govitecan-hziy) Storage and Stability (Reconstituted and Diluted)

This document is in response to your request for information on the in-use storage and stability of Trodelvy® (sacituzumab govitecan-hziy [SG]) following reconstitution and/or dilution. This does not intend to offer an opinion regarding the clinical relevance of these data or the advisability of storing or administering any drug in a manner inconsistent with its approved labeling. SG should be stored according to the product label.

Some data may be outside of the US FDA-approved prescribing information. In providing this data, Gilead Sciences, Inc. is not making any representation as to its clinical relevance or to the use of any Gilead product(s). For information about the approved conditions of use of any Gilead drug product, please consult the FDA-approved prescribing information.

The full indication, important safety information, and boxed warnings for neutropenia and diarrhea are available at: **www.gilead.com/-/media/files/pdfs/medicines/oncology/trodelvy/trodelvy_pi.**

Relevant Product Labeling[1]

Dosage and Administration

Reconstitution

Using a sterile syringe, slowly inject 20 mL of 0.9% Sodium Chloride Injection, USP, into each 180 mg SG vial.

Gently swirl vials and allow to dissolve for up to 15 minutes. Do not shake. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. The solution should be free of visible particulates, clear and yellow. Do not use the reconstituted solution if it is cloudy or discolored.

Use reconstituted SG immediately to prepare a diluted SG infusion solution.

Dilution

Use 0.9% Sodium Chloride Injection, USP only since the stability of the reconstituted SG solution has not been determined with other infusion-based solutions. Use a polyvinyl chloride, polypropylene/polyethylene, polyolefin, or ethylene vinyl acetate infusion bag.

To minimize foaming, slowly inject the calculated amount of reconstituted SG solution into the infusion bag. Do not shake the contents.

If not used immediately, the infusion bag containing SG solution can be stored refrigerated at 2°C to 8°C (36–46°F) for up to 24 hours protected from light. After refrigeration,

administer diluted solution at room temperature up to 25°C (77°F) within 8 hours (including infusion time).

Do not freeze or shake.

Alternative Storage and Stability Information

Data from in-use stability, compatibility, and microbial challenge studies support the following statements below related to reconstituted SG in vials and ground transportation of diluted SG in IV bags.[2]

These statements solely relate to the in-use stability, compatibility and microbial challenge studies and do not endorse use of SG beyond these conditions, or the expiration date stated on the original packaging.[2]

Please note, the total allowable hold time for the entire process i.e. from SG reconstitution in 0.9% saline, dose preparation in IV bags, hold of diluted SG (1.1 and 3.4 mg/mL) in 0.9% saline and administration, should not exceed a cumulative of 24 hours at 2–8°C and 8 hours at room temperature.[2]

Reconstituted SG[2]

In an in-use stability study, SG vials were reconstituted with 0.9% sodium chloride to achieve a nominal concentration of 10 mg/ml.

Data from this study supports the stability of reconstituted SG in 0.9% sodium chloride (at 10 mg/mL) up to 8 hours at room temperature or up to 24 hours at 2–8°C (36°F to 46°F).

Ground Transportation[2]

In an in-use stability study, SG was diluted to 1.1–3.4 mg/mL in 0.9% sodium chloride. Data from this study supports the statement that ground transportation of prepared SG IV is allowed for up to 4 hours at 2–8°C.

References

1. TRODELVY® Gilead Sciences Inc. Trodelvy (sacituzumab govitecan-hziy) for injection, for intravenous use. U.S. Prescribing Information. Foster City, CA.
2. Gilead Sciences Inc. Data on File.

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Trodelvy US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/oncology/trodelvy/trodelvy_pi.

Follow-Up

For any additional questions, please contact Trodelvy Medical Information at:

☎1-888-983-4668 or 🖱 www.askgileadmedical.com

Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or
🖱 www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🖱 www.accessdata.fda.gov/scripts/medwatch

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